

Remarks:

Applicants note with appreciation the allowance of claim 2.

Claims 9 and 10 have been objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form. Applicants respectfully request that the Examiner reconsider this objection and allow these dependent claims based on the arguments presented below demonstrating the patentability of claim 8.

Claim 8 stands rejected under 35 USC 102(b) as being anticipated by Mazel (U.S. Patent 5,704,936). Applicants respectfully traverse this rejection.

Initially it must be stated that there is so little in common between the claimed invention and the Mazel reference that it is almost impossible to formulate a rational response. Because there are so few comparable elements between the claimed invention and Mazel, any attempt to explain the distinction between the two must necessarily include lengthy descriptions to describe elements which pictorially are so clearly unrelated.

The major difficulty in responding rationally to the Examiner's rejection is that the Examiner's assumptions about the teachings of Mazel are not borne out by the descriptions used by Mazel in the cited reference. It appears that the best way to demonstrate the difference between Mazel and the claimed invention is to break down the Examiner's explanation into components and respond to each component.

A) The Examiner states that "Mazel discloses a system capable of retaining a graft in a bone tunnel..."

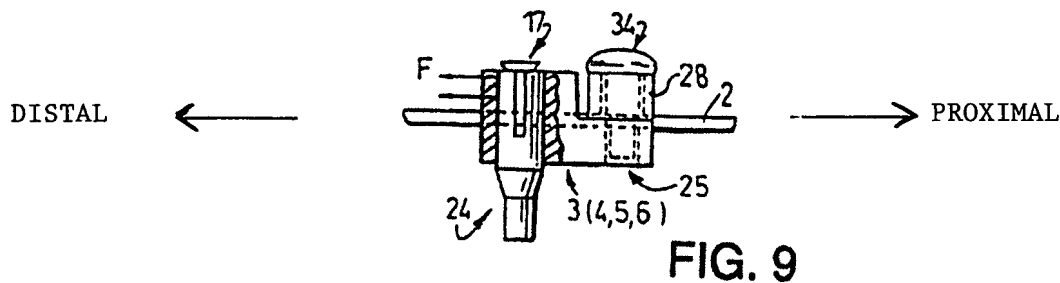
Mazel does not suggest retaining a graft at all, much less in a bone tunnel. Mazel relates to a device which holds bones together, in particular spinal vertebrae. Accordingly, there is no

teaching in Mazel that a bone tunnel could be used for anything. The closest thing to a tunnel that the Mazel device can produce is a hole formed by a screw threaded into the spinal vertebrae. There is no suggestion that once this hole is formed the screw should be removed and something else such as a graft should be put in its place. The screw simply stays where it is screwed in. Accordingly, Applicants see no feature of Mazel which is capable of producing a tunnel or retaining a graft in a bone tunnel. The Examiner is respectfully requested to particularly point out where the Mazel bone tunnel is.

Mazel does not relate to attaching graft ligaments to bone. Rather Mazel relates to a spinal osteosynthesis device intended for treating scolioses, tumors, fractures and degenerative pathologies. In particular, Mazel relates to fitting plates and rods to spinal vertebrae through the use of bone anchoring elements allowing slidable retention of wire rods. There is no reason for the Mazel device to utilize a bone tunnel or graft and, accordingly, there is no suggestion or disclosure of anything in Mazel that could be remotely considered a graft or bone tunnel.

B)...comprising a graft block (Fig. 9) having a proximal end and a distal end,...

Whatever the Mazel device is in Figure 9 it is not a graft block for retaining a graft in a bone tunnel as is required by the claimed invention. Mazel's device simply holds two wire rods 2 and connecting members 3, 4, 5 and 6 to the surface of bone: in particular, to the surface of the vertebrae. The device shown in Mazel's Figure 9 can admittedly be described as having proximal and distal ends, and Applicants will attempt to use that terminology here. From statements made by the Examiner below it is assumed that "distal" means to the left of Figure 9 and proximal means to the right.



C)...the graft block including a distally facing, saddle-shaped graft support surface (Fig. 7, ref #26) at the distal end for supporting the graft,...

Using this definition of "distal" the Examiner refers to an element number 26 as being a saddle shaped graft support surface. It is respectfully pointed out that this is simply incorrect.

Element 26 in Mazel is either a conical portion of a pinnacle screw (column 4, line 28; this is believed to be a typographical error) or a protrusion on the short side of an L-shaped profile of a connector (column 4, line 38). Applicants assume that the Examiner is referring to Figure 6 of Mazel which shows a protrusion having a curved outer surface. This surface is distally facing using the above convention, however, the only similarity between the saddle shaped graft support surface of the claimed invention and the curved surface of element 26 is that they are both curved. The surface of element 26 does not support anything. It does not even touch anything. It is merely provided to produce enough material through which a screw hole 27 could be formed.

Furthermore, there is no graft in Mazel for anything to support. One can, of course, imagine a graft supported by element 26. But to suggest that just because this curved surface faces

upward (Mazel Figure 1) it could support a graft placed on it is incredulous. The only thing supported by the device in Figure 9 is two rods and these are not even remotely analogous to graft ligaments which are the subject of the claimed invention.

Assuming, arguendo, that the Examiner is referring to rods 2 as a graft, it is clear from Mazel Figure 10 that there is no contact between element 26 and rods 2, and therefore no support by any saddle-shaped surface as required by the claims.

D)... the graft block being sized to slidingly fit within the bone tunnel,....

Again, there is no bone tunnel shown or suggested by Mazel. Accordingly, there is nothing shown which slidingly fits within a bone tunnel. There is no suggestion or disclosure that the device of Figure 9 fits into anything. The device is intended only to be attached to the surface of bone, not into a tunnel in the bone.

E)...the graft block further comprising a transverse proximally-facing abutment surface, the abutment surface comprising a proximally facing open groove (see Fig 7, groove formed at ref# 25b) formed transversely across the proximal end of the graft block, generally parallel to the graft support surface and located proximal to the graft support surface;...

It appears that the Examiner is referring to grooves 32 formed in the long side of the L-shaped profile of the connector of Figure 6. In view of this, the Examiner must be referring to the surface in which the grooves are formed as being the proximal end of the graft block (this is the surface in which hole 33 is formed). It is possible the Examiner is defining features in this way in order to analogize the wire rods which fit in grooves 32 to a graft so that this surface can then be called a graft support surface. Such a literal mechanical interpretation of elements of any device does not give any credit to Applicants' definitions of elements which must be applied in order to properly understand the claimed invention. Nevertheless, assuming the proximally

facing open grooves referred to by the Examiner are grooves 32, there is an inconsistency in the way the terms “proximal” and “distal” are used. As explained above in paragraph B the term “distal” refers to the left in Figure 9. To be consistent with this, the term “proximal” would have to be to the right. However, the “proximally-facing abutment surface” defined in this paragraph E, i.e. grooves 32, necessarily faces upward in Figure 9, neither to the right (distal) or left (proximal). Consequently, if the proximal/distal convention in paragraph B is correct then this definition of “abutment surface” is incorrect, and vice versa.

In the claimed invention, as best seen in Figures 26-29 of the application, the graft support surface 1732 and the open groove 1736 face in opposite directions. This is clearly reflected in claim 8. No comparable elements are shown or suggested by Mazel.

F)...a tunnel attachment means (ref # 34) engages transversely with the bone tunnel and the abutment surface of the graft block to support the graft block in the bone tunnel,...

Element 34 is a screw (Figure 6) to be received in hole 33 (Figures 6 and 9). Putting aside for a moment the aforementioned inconsistency in the proximal/distal terminology, the screw 34 does not engage a bone tunnel. It does not even engage bone. It also does not engage the “abutment surface” as that term is defined by the Examiner (the surface in which hole 33 is formed), but goes through that surface. Moreover, screw 34 does not support the graft block (Figure 9) in a bone tunnel. The device of Figure 9 is nowhere shown to be in any bone, but only on the surface of bone.

G) ...the tunnel attachment means being located proximally of the graft support surface such that tensile forces on the graft result in compressive forces on the graft block between the graft support surface and the tunnel attachment means;...

The tunnel attachment means as defined by the Examiner is screw 34. Given the definition of “distal” being to the left in Figure 9 it is correct to say that screw 34 is proximal to what the Examiner calls the graft support surface (the curved outer part of element 26). However, because there is no graft supported by element 26, the remainder of this component of the Examiner’s explanation is missing. Even if the Examiner is correct to analogize wire rods 2 to a graft, as clearly shown in Mazel’s Figures 8 and 10 there is no contact between element 26 and rods 2. Consequently, the Examiner’s “graft” cannot exert any proximally directed forces on the device of Figure 9 to create compression between the surface of element 26 and the screw 34.

H) ...and a pair of distally extending sockets (ref 32) is formed in the proximal end of the graft block within the open groove.”

The element 32 is a groove facing laterally relative to the proximal/distal definition established above. Even if one were to say this is the equivalent of the claimed sockets, the location is not “within the open groove”. The term “open groove” refers to a proximally facing portion of the claimed abutment surface. Element 32 is not within anything that could be deemed comparable to an open groove if for no other reason than it faces the wrong way. The end of groove 32 facing to the right in Figure 6 is the part the Examiner is calling a socket. However, as the term “socket” implies and as used in the application, there should be something to be received in the “socket”, preferably through its open end, in line with the axis of the socket. There is absolutely no suggestion that this structure, that is, the end of the grooves 32, can act as a socket to receive anything. Such a socket would be expected to receive something being pushed into it in a direction generally parallel to the groove surface. But there is no such

structure shown or suggested. Even the rods 2 received in the grooves 32 are not inserted this way. They are laid in the grooves and clamped with a cover plate held by screw 34.

Applicants believe they have demonstrated the distinction between Mazel and claim 8 in significant detail and respectfully request that the Examiner reconsider the rejection of claim 8.